

*In re: Roberts et al.*  
*USSN: 09/826,609*  
*Filed: April 5, 2001*  
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### **REMARKS**

Claims 1-5, 7 and 25 have been amended herein. Support for these amendments is found throughout the specification. As such, no new matter has been added by these amendments.

Claims 1-26 are pending in the subject application. Claims 8-24, drawn to non-elected inventions, are withdrawn from consideration. Claims 1-7, 25 and 26 are examined on the merits.

### **Priority**

The Examiner correctly notes that Applicants claim priority to 60/103,220 ('220) filed on October 5, 1998. Applicants strongly traverse any attempt to modify the priority date for the presently claimed invention by the Examiner. Applicants consider it wholly inappropriate that the "instant application will be given the instant U.S. filing date of October 5, 2001" and ask that such comment be stricken from the record.

First, in the absence of intervening prior art, questions of priority are not properly raised or addressed by the USPTO:

The only times during *ex parte* prosecution that the examiner considers the merits of an applicant's claim of priority is when a reference is found with an effective date between the date of the foreign filing and the date of filing in the United States and when an interference situation is under consideration. MPEP §201.15

Applicants note that the art cited in reference to 35 USC §102 and 35 USC §103 have priority dates in advance of October 5, 1998 (Boon et al., shows dates ranging from 23 May 1991-22 May 1992; Maraskovsky et al., is afforded 10 July 1996) and thus, neither the date of the '220 priority application or the October 5, 2001 filing date for the instant application is at issue.

Second, the '220 provisional document contains subject matter that is found in the instant application. There is language and many examples throughout the '220 and

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instant applications which are identical or substantially similar; as one example Applicants note Fig. 4A & 4B of '220 is found in the present application as Fig. 1A & 1B. Applicants may or may not choose to pursue such subject matter in a continuation application. Hence, the date of the "instant application" is not and cannot properly be considered October 5, 2001.

Third, cdc2-related protein kinase or integrin alpha-3 are relevant to the inventions instantly claimed herein. These are exemplified species whose identification was illustrated by the use of the instantly claimed methods. Hence, regardless of scope of the originally filed case, October 5, 1998, is a filing date which is relevant and properly applied to the instantly claimed subject matter.

Notwithstanding the foregoing, Applicants note the helpful suggestion by the Examiner to clarify the priority claim from PCT/US99/23166. Accordingly, Applicants have amended the specification.

#### **Oath/Declaration**

A revised form of Oath/Declaration is provided herewith in accord with the clarification to the priority claim. An executed copy will be submitted as soon as signatures are collected from the inventors.

#### **Claim Rejections – 35 USC §112**

Claims 2, 3, 4, 5 and 7 stand rejected under 35 U.S.C. §112, second paragraph, under argument that they are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants assert that the above amendment to the claims fully address the rejections of record and render these rejections moot.

#### **Claim Rejections – 35 USC §102**

Claims 1-7 and 25 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Boon et al (WO 92/20356). These rejections are traversed as follows.

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The present invention is drawn to a method to identify a putative cancer therapeutic using a series of defined method steps in a proscribed order. The advantage of the instant method is the generation of high quality targets useful as a putative cancer therapeutic. The method calls to first identify polynucleotides which are uniquely expressed or overexpressed in a target human cancer cell as compared with a control. Thus, some method of gene expression analysis is required. The second step requires the correlation of the polynucleotide with its corresponding protein. The third step calls for the determination if the protein, or fragment, is immunogenic.

While Boon also seeks to identify a putative cancer therapeutic, as set forth in Example 1, he seeks to identify and isolate a specific gene coding for the antigen P815A, a murine gene. A closer reading of Example 1 shows that the source of the gene was transfected into the cell line P1.HTR. Other manipulations were conducted to optimize the starting material, but the point is that no control (as required by the claims) was generated for the comparison of gene expression profiles. Even assuming *arguendo* that there is some identification of a polynucleotide which is uniquely expressed or overexpressed in a target cancer cell, the presently claimed invention requires the comparison of a target cancer human cell with a control non-cancer human cell.

Moreover, insofar as Boon is applied to claim 7, it is readily apparent that the feature of the claim which requires "an amino acid sequence which is not previously known to be antigenic" is not met.

In view of the foregoing, Applicants respectfully request removal of these grounds of rejection.

#### **Claim Rejections – 35 USC §103**

Claims 1-7, 25 and 26 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Boon et al (WO 92/20356) in view of Maraskovsky et al (US 6,017,527). These rejections are traversed as follows.

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As discussed above, Boon differs from the presently claimed invention in several aspects. None of the above-noted deficiencies are cured by the secondary reference, Maraskovsky.

Moreover, even assuming arguendo that somehow the above-noted deficiencies are properly addressed, there is no suggestion or teaching in Boon or Maraskovsky which would lead one of skill in the art to combine the references in the manner suggested by the Examiner. The teaching in Maraskovsky of compositions and methods to prepare activated dendritic cells without more does not explain how or why one of ordinary skill would make the suggested combination.

Thus, Applicants respectfully request removal of this ground of rejection.

**Conclusion**

In view of the foregoing, it is believed that this application is in condition for immediate allowance. If the Examiner considers that a telephone conference may be useful, please contact the undersigned at the numbers provided below

If any additional fees are deemed necessary in connection with the filing of this communication, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,

March 10, 2004  
Date

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